REMARKS

I. Prosecution History.

The application as filed contained 11 claims. Claims 3, 4, 7, and 10 have been canceled without prejudice, claims 1, 2, 5, and 8 have been amended herein, and new claims 12 and 13 have been added. In the Official Action (Paper No. 10) dated October 3, 2002, the claims were restricted, the applicant's claim of priority was not granted, the specification was objected to, English abstracts of Japanese references were not considered, and claims 1, 2, 5, 6, 8, and 9 were variously rejected under 35 U.S.C. 101 and 112. Applicants respectfully traverse the restriction requirement and the rejections.

II. Response to Restriction Requirement

The Office Action dated October 3, 2002 set forth a two-way restriction requirement as follows:

Group I: Claims 1, 2, 5, 6, 8 and 9 drawn to a polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1; and

Group II: Claims 3, 4, 7, 10 and 11 drawn to a nucleotide sequence which encodes a collectin protein.

While the Examiner contends that a telephonic election without traverse was made by Attorney David Gass on June 26, 2002, the election was in fact made with traverse by the undersigned agent. Applicants elect the invention of Group I, *i.e.*, claims 1, 2, 5, 6, 8 and 9. This election is made with traverse.

III. Traversal of Restriction Requirement

This application was filed in accordance with 35 U.S.C. §371, as a national phase application of PCT application No. PCT/JP99/03328. Accordingly, unity of invention practice is applicable. Applicant respectfully requests that the restriction requirement be reconsidered in accordance with the Written Opinion and International Preliminary Examination Report received from the International Searching Authority for PCT/JP99/03328 (see Appendix A, previously submitted to the Office on

September 8, 2002). In the aforementioned Opinion and Report, the application was found to have unity of invention for Claims 1-11 as originally filed. The claims of Groups I and II are both directed to collectin proteins and polynucleotides which encode collectin proteins. Thus, for the foregoing reason, applicant requests that the restriction requirement be reconsidered and withdrawn.

IV. The Applicant's claim for foreign priority under 35 U.S.C. §119 should be granted.

A certified English translation will be provided to support the priority date claimed.

V. The IDS.

At page 4 of the Office action, the Examiner did not consider the properly identified English abstracts of Japanese references which were supplied in the IDS. The Examiner lined through the listing of these references to the properly identified English abstracts of Japanese references on the returned form 1449 as if they were not considered. Applicants submit that these properly listed English abstracts should have been considered and respectfully request that this be noted in the record. A duplicate copy of form 1449 is submitted herewith for this purpose.

VI. The Objection to the Specification.

At page 5 of the Office action, the Examiner objected to the specification for not entering the "continuing data" on the first page, first line of the specification. As the examiner notes, this application was filed in accordance with 35 U.S.C. §371, as a national phase application of PCT application No. PCT/JP99/03328. The application is not a continuing application under §120 of the statute. Accordingly, no such requirement is specified in the statute or the rules. If the applicant's are in error, the Examiner is requested to specifically point out the appropriate rule or statutory provision.

VII. The Patent Office's rejection of claims 1, 2, and 8 under 35 U.S.C. §101 should be withdrawn.

At page 5 of the Office action, the Patent Office rejected claims 1, 2, and 8 under 35 U.S.C. § 101 and suggested that that these claims should refer to "isolated" polynucleotides (claims 1 and 2) and collectin proteins (claim 8). These claims have been amended in accordance with the Examiner's suggestions. The applicant's, therefore, request that the rejections based on 35 U.S.C. § 101 should be withdrawn.

VIII. The Patent Office's rejection of claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Examiner has rejected claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention. While the Examiner has rejected these claims, the Examiner admits that applicant's were in possession of the polynucleotide of SEQ ID NO:1 and the polynucleotide encoding the amino acid sequence of SEQ ID NO: 2. In the office action, the Examiner provides no reasoning or explanation as to why claims 1, 2, 6, and 9 are rejected under 25 U.S.C. 112, first paragraph. Thus, the rejection of these claims should be withdrawn. Instead, the Examiner only provides reasoning with regards to claims 5 and claim 8.

With regard to claim 5, the Examiner contends that it encompasses subject matter that is not defined in the specification. Specifically, the Examiner stated that the Applicants have given no concise definition of the terms listed as (1) a Ca^{2+} dependent carbohydrate recognition domain (CRD), (2) a neck region, (3) a collagen-like region and (4) an N-terminal region containing cysteine, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention (Page 6 of the Office Action).

Applicant respectfully disagrees. At the filing date of this application, persons of ordinary skill in the art knew that collectins have structures comprising features (1)-(4) above. For example, page 1, lines 22-23 of the specification cites, Malhorta *et al., Eur. J. Immunol.*, vol. 22, pp. 1437-1445 (1992), which refers to regions (1)-(4) as follows:

> the polypeptide chains of SP-A consist of a short N-terminal segment, followed by a region of collagen-like sequence . . . The C-terminal half of the sequence is non-collagenous, and contains, in SP-A, a structure known as a C-type lectin domain, indicating that the protein exhibits calcium ion-dependent binding to carbohydrates . . . The non collagenous C-terminal halves form a globular "head". (Page 1441, Col. 2).

As evidenced by the art cited in the specification and considered by the Examiner, these terms were known to and understood by persons of skill in the art, and therefore, the rejection should be withdrawn.

The Examiner also contends that:

> no guidance is provided to determine what are those polynucleotides, which can hybridize with the polynucleotides that encodes a protein that comprises (1) a Ca^{2+} dependent carbohydrate recognition domain (CRD), (2) a neck region, (3) a collagen-like region and (4) an N-terminal region containing cysteine. There is no description of the function of these polynucleotides and the protein encoded by them and the structural information is also limited. Therefore there is lack of written description as to what are those polyucleotides and the polypeptides encoded by them, which have some activity related to the activity of collectin protein (Page 6 of the Office Action).

Applicant respectfully disagrees. Claim 5 has been amended consistent with Example 9 of the PTO's Training Materials for the Interim Written Description and Utility Guidelines. In addition, in Examples 1-4 of the specification the claimed polynucleotide is obtained by the steps comprising: 1) identifying molecules with highly conserved regions with the collectin set out in SEQ ID NO: 3 (see Example 1), preparing probes from the clones so obtained for screening (see Example 2), screening by hybridization a cDNA library from human liver for complementary polynucleotides (see Example 3), and determining the base sequences of the cDNA (see Example 4). It should be noted that the Applicant succeeded in Example 3 through screening-by-hybridization to isolate polynucleotides which hybridize with the probes prepared in Example 2. From this process, the specification teaches one of ordinary skill in the art how to isolate the polynucleotides of claim 5. Proteins encoded by the polynucleotides of claim 5 have been shown have the same activities

(e.g., anti-viral activity, immuno-enhancing activity) as known collectins. Claim 5 as amended, is now directed to a polynucleotide that has the sequence properties to hybridize under the specified conditions and therefore the rejection should be withdrawn.

Finally, with regard to claim 8, the Examiner contends that:

> "Claim 8 is assumed to have been a method of treating claim. The scope of said claim is vastly in excess of the single embodiment provided in page 6-7 of the instant disclosure. Without additional test data, extrapolation beyond that example is not adequately supported in the specification (Page 6 of the Office Action).

Claim 8 is a proper composition of matter claim directed to an isolated collectin protein comprising the amino acid sequence set out in SEQ ID NO: 2. Without further clarification for the reasons for rejection, the rejection should be withdrawn

IX. <u>The Patent Office's rejection of claim 5 under 35 U.S.C. §112, second paragraph, should be withdrawn</u>.

With regard to claim 5, the Examiner contends that:

> "Claim 5 is indefinite because the use of the term 'hybridize' is not clear. Recitation of the stringent hybridization condition in the claim will overcome the rejection. Claim 5 is indefinite because the first part of the claim requires polynucleotide to hybridize with the polynucleotide of claim 2 and second part of the claim requires the said polynucleotide to encode a protein of claim 2. If the polynucleotide of claim 5 is a non-coding strand then it hybridizes with the complement that is coding strand of the polynucleotide of claim 5. If the coding strand of claim 5 encodes the same protein of claim 2, then it cannot hybridize with the polynucleotide of claim 5. (Page 6 of the Office Action.)

Applicants have adopted the examiner's suggestion. Claim 5 has been amended to recite a polynucleotide that hybridizes to a noncoding strand that is complementary to SEQ ID NOS: 1 and 2 under the stringent hybridization conditions disclosed in the specification (see Example 3). In light of this amendment, the rejection should be withdrawn.

CONCLUSION

It is submitted that all claims are now in condition for allowance. Applicant respectfully requests an early and favorable notification thereof. Should the Examiner wish to discuss this response in further detail in an effort to advance this application toward allowance, the Applicants invite the Examiner to telephone the undersigned representative at the indicated number.

Respectfully submitted,

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